DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
New Orleans District Compliance
d1684b

4298 Elysian Fields Avenue
New Orleans, LA 70122

December 20, 1996

WARNING LETTER NO. 97-NOL-21

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. N. Edward Hakins, President
Luv'n Care, LTD.
2813 DeSiard Street
Monroe, Louisiana 71201

Dear Mr. Hakins:

During an inspection of your firm, located in Monroe, Louisiana, on 10/31-11/5/96, our investigators determined that your firm is the Specification Developer and Distributor of water filled soothers (teething rings). Teething rings are devices as defined by Section 201(h) of the Federal Food, Drug and Cosmetic Act (the Act).

The above stated inspection revealed that these devices are adulterated within the meaning of Section 501(h) of the Act, in that the methods used in, or the facilities used for manufacturing, packaging, storage, or installation, are not in conformance with Good Manufacturing Practice's (GMP's) for Medical Device Regulations, as specified in Title 21, Code of Federal Regulations (CFR), Part 820, as follows:

1. Failure to institute a Quality Assurance program for identifying, recommending or providing solutions for quality assurance problems and verifying the implementation of such solutions;

2. Failure to maintain written records of investigations, including conclusion and follow-up, in response to consumer complaints of device failures.

Six of eleven complaints received since 1/96, lacks documentation of device failure investigation and follow-up. Firm did not document through investigation and/or testing that the black particles present in the complaint teethers was Stemphilium or Sepedonium or that the empty (waterless) teethers were actually due to evaporation

because of age and not caused by pin holes, seam defects, or brittle plastic due to the gama sterilization.

The manufacture and distribution of adulterated and misbranded medical devices is prohibited under Sections 301(a) and 301(k) of the Act.

The above identification of violations is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure adherence with each requirement of the Good Manufacturing Practice Regulations of the Federal Food, Drug and Cosmetic Act. You should take prompt action to correct these and all violations existing at your firm. Failure to take such action may result in regulatory action, such as seizure, without further notice. Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts.

You should notify this office in writing, within 15 working days of receipt of this letter, of the steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason for this delay and the time within which the corrections will be completed.

Your response should be directed to Carolyn S. Olsen, Compliance Officer, U.S. Food and Drug Administration, 4298 Elysian Fields Avenue, New Orleans, Louisiana, 70122-3848, telephone number (504) 589-7166. Should you have any questions concerning the contents of this letter, or if you desire a meeting with the agency staff, do not hesitate to contact Mrs. Olsen.

Sincerely,

for

James E. Gamet
District Director
New Orleans District

Enclosure: FDA-483

cc: [redacted]